REMARKS

Reconsideration of this application, as amended, is respectfully requested. Claims 16, 17 and 21 have been amended. New claims 30-41 have been introduced. With this amendment, claims 16, 17, 19-22, and 30-41 are currently pending. These amendments are made without prejudice or disclaimer, do not add any new matter, and find support in the originally filed application. Applicants reserve the right to reincorporate any cancelled or otherwise presently unclaimed subject matter in this application or to prosecute the same in subsequently filed applications. Consideration and entry of this amendment is respectfully requested.

AMENDMENT TO THE CLAIMS

Applicants have amended the claims in order to place the same in condition for allowance. As amended, claims 16, 17 and 19-22 relate to compositions and methods of using a protein encoded by SEQ ID NO.: 23. New claims 30-35 relate to compositions and methods of using a protein of SEQ ID NO.: 24. New claims 36-41 relate to compositions and methods of using a V38 truncation of SEQ ID NO.: 24 as illustrated in, for example, Fig. 8B. This V38 truncation was also shown to be immunogenic and at least partially protective against infection by NTHi strain 33 in, for example, Examples 11 and 13. The subject matter of claims 16, 17, 19-22 and new claims 30-35 was indicated to be allowable. The subject matter of new claims 36-41 refers only to a particular V38 truncation having a clearly described amino acid sequence. Accordingly, Applicants believe these amendments address all of the rejections set out in the June 18, 2009 Final Office Action.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 16-22 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claim 16 has been amended such a Markush Group is not necessary. Claims 16(c) and (d) have been cancelled. The preamble of claim 16 that referred to "producible" has been deleted. Accordingly, these rejections are moot.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 16-22 stand rejected under 35 U.S.C. § 112, first paragraph as not being enabling for the subject matter of parts (c) and (d) of claim 16. Parts (c) and (d) of claim 16 have been cancelled; that portion of the rejection is therefore moot.

The rejection states that the "specification fails to demonstrate that any of the polypeptides recited in parts (a)-(d) of claim 16 meet any of the three considerations known in the art to be important when considering a bacterial antigen as a vaccine candidate." The rejection also states that "[t]he specification only enables the polypeptide set forth in SEQ ID NO:24 or one encoded by the nucleic acid sequence set forth in SEQ ID NO:24…[and not] variants of these sequences." Accordingly, Applicants understand the rejection to apply only to the subject matter of previously pending parts (c) and (d) of claim 16, which have been cancelled without prejudice in this amendment. The subject matter of new claims 36-41 relates in part to previously pending part (c) (e.g., a species thereof). As noted by the Examiner, Applicants have previously pointed out that the V38 rHia(33) compositions were shown in Examples 11 and 13, for example, to induce significant anti-V38 rHia antibody responses and to provide at least partial protection against infection by NTHi strain 33. Applicants believe the Examples show that the vaccine "considerations" referred to in the rejection would be understood by one of skill in the art to be satisfied by the claimed V38 rHia(33) compositions and methods (e.g., new claims 36-41). Regarding other species of *Hemophilus*, the relevant claims have been amended to specifically refer to *Hemophilus influenzae* non-typeable strain 33, which means that the immunogenic composition will <u>at least</u> protect against disease caused by that strain. This does not mean, however, that the compositions will not also protect against other species or strains that express related polypeptides.

As stated at MPEP 2164.01(a):

> It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the [Wands] factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole.

The Wands factors include (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and, (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In this rejection, none of the Wands factors have been specifically discussed which is in itself improper. However, in order to expedite prosecution, Applicants address each of these factors below.

Applicants believe all of the *Wands* factors are satisfied by the amended claims, including new claims 36-41. Regarding factor (A), the claims are directed to nucleic acids encoding and / or polypeptides having particular amino acid sequences. The nature of the invention (B) and the state of the prior art (C) are such that the claims are not of undue breadth. While some experimentation may be required to formulate the compositions and determine the exact dosages required induce an immune response, such experimentation is well within the reach of the skilled artisan in this field, which is typically a highly skilled individual (factor D). Given the limited nature of the claimed subject matter (e.g., compositions comprising and methods for using particular polypeptides), the level of predictability of the claimed subject matter is high relative to vaccine field (factor E). The specification provides ample guidance to one of skill in the art seeking to practice the claimed invention (factor F, G). For instance, the sequences of the nucleic acids or polypeptides and methods for preparing the same are clearly described in the specification (e.g., Examples 7-9) and the claims. And the specification (e.g., p. 28-35, Examples 11 and 13) describe methods of administering the claimed compositions and measuring the resultant immune responses. Given all of this information, the quantity of experimentation needed to make or use the claimed subject matter, while not zero, certainly cannot be said to be undue (Factor H). Accordingly, Applicants respectfully maintain that the pending claims are enabled by the instant specification as required by 35 U.S.C. § 112, first paragraph. As such, it is respectfully requested that these rejections be withdrawn.

CONCLUSIONS

Applicants believe the claims are in condition for allowance and respectfully request that a Notice of Allowance be issued as soon as possible. The Examiner is encouraged to contact the undersigned with any comments and / or questions.

Respectfully submitted,

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